

REMARKS

Claims 1-6, 9-11, 14-21, 23-38, 40-48, 50-56, and 58-103 are in the application. Claim 1 is amended to incorporate the limitations of claim 22, which is accordingly canceled. Claims 1, 5, 9, 14-21, 23, 24, 32, 36-38, 40-46, 52-56, 58-60, 63-65, 68-70, 75, 77, 81-83, 91-94, 96, 97, and 100 are amended to overcome various objections/rejections, as discussed below. Claims 7, 8, 12, 13, 39, 49, and 57 are canceled in response to various objections/rejections, as discussed below. New claims 102 and 103, which depend from claims 99 and 101, respectively, are added.

The Abstract is objected to for containing “legal phraseology, such as ‘means’ language”.

The Abstract is amended to delete “means” associated with emitter.

The Abstract should now be clear of objections.

Claims 12-13, 16-17, 21-22, 24, 35-49, 54-55, 57-58, 63-64, 68-70, 77, 82-83, 92-94, 97, and 100 are objected to for various informalities, as discussed serially below. Claims 12-13, 22, 39, 49, and 57 are canceled.

(A) Claims 12-13, 16, 22, 55, 63-64, and 82 are objected to for being unclear if the emitter stated therein relates to the emitter in claim 1.

The emitter in these claims is the same as “emitter means” in claim 1. The term “means” is deleted from claim 1, thereby making it clear that the emitter recited in the dependent claims is the same emitter recited in claim 1. Further, claim 1 is amended to recite “at least one emitter”, and claims 16, 17, 24, 59, and 82 are amended to refer to “said at least one emitter”. Claims 14, 15, 18, and 19 are likewise amended.

Claim 20 recites a plurality of the emitters of claim 1, and is amended to clarify this aspect of the invention. Claim 21 refers to the plurality of emitters of claim 20, and is also amended for clarity on this point.

Claim 55 is amended to clarify that an output of the at least one emitter of claim 1 is mechanically scanned.

Claims 63-64 are amended to clarify the reference to the at least one emitter of claim 1.

(B) Claims 17, 21, and 24(d) are objected to as reciting functional language without associated structure.

Claim 17 is amended to recite that the at least one emitter has at least one operating characteristic that is selected from the recited group.

With regard to claim 21, Applicants can find no so-called functional language, and the Examiner has not specifically pointed to such functional language. Claim 21 recites different arrangements of the at least one emitter. If the Examiner would specifically point to the alleged problem, Applicants will attempt to address the issue.

With regard to claim 24(d), this portion of the claim recites what the emitter can emit, in parallel to elements (a), (b), and (c). Again, if the Examiner would specifically point to the alleged problem, Applicants will attempt to address the issue.

(C) Claim 35 is objected to for reciting the use of at least one of a drug, medicament, vitamin, or mineral or controlled dietary matter or content. Claims 36-49, 54, and 68-70 are similarly objected to.

Claim 1 is amended to specify that the patient is “optionally receiving a substance”, and claim 35 is amended to recite that the substance comprises at least one of a drug, medicament, vitamin, mineral or controlled dietary matter or content.

Claims 36-38, 40-45, 49, 54, and 70 are amended to recite “said drug, medicament, vitamin, mineral or controlled dietary matter or content”, and to make the language consistent. Claims 46, 54, 68, and 69, which depend from claim 1, are amended to specify “said substance” and then to recite the substance (as identified above).

Independent claim 91 is amended to recite “a substance”, which is identified as above. Claims 92-94 is amended to be consistent with the language of the substance. Claim 96 is amended to provide appropriate antecedent basis.

(D) Options (a), (b), (c), (d), and (e) of Claim 39 are objected to as being irrelevant since the substance reaches a brain or neurological region by passing through the BBB unaided.

In accordance with Applicants’ teachings, the use of the emitter to treat neurodegenerative diseases, in combination with a cooling device, is at the heart of their invention. Optionally, a substance, such as a drug, medicament, vitamin, mineral or controlled dietary matter or content may be employed in conjunction with the apparatus to aid in the treatment. However, it is not intended, nor is it claimed, that the substance may be used unaided. Thus, upon reflection, claim 39 is canceled, since the aided aspects are subsumed within claim 1.

(E) Claim 49 is objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 49 is canceled, thereby obviating the objection.

(F) Claims 57-58 are objected to as failing to further limit the subject matter of previous claim 56.

Claim 57 is canceled. Claim 58 is amended to specify that the structure has one or more of an umbilical, cable or coolant lumen which connects or is connectable to the system, thereby further limiting claim 56, from which claim 58 depends.

(G) The Examiner indicates that claim 77 should read “The system of claim 1, wherein --at least one of--“.

The Examiner is correct, and claim 77 has been so amended.

(H) Claim 82 is objected to as being unclear.

Claim 82 has been amended to be consistent with amended claim 1.

(I) Claim 83 is objected to as being an intended use as well as failing to provide for beam-forming or beam-steering.

Claim 83 is amended to depend from claim 17, which provides antecedent basis for the beam-forming or beam-steering. Claim 83 is also amended to overcome the intended use objection.

(J) Claims 94 and 97 are indicated as system claims, but depend from a method claim.

Claims 94 and 97 are amended to recite “The method of ...”.

(K) Claim 100 is objected to for the phrase “administration of acoustic or vibrational energy, whereas the subsequent method steps call for acoustically enhancing or enabling.

Claim 100 is amended to insert “or vibrationally” after “acoustically” in each of steps (i), (ii), (iii), and (iv).

Reconsideration of the objection to claims 16-17, 21, 24, 35-38, 40-48, 54-55, 58, 63-64, 68-70, 77, 82-83, 92-94, 97, and 100, as amended, is respectfully requested.

Claims 7, 8, 12, 13, 24, and 65 are rejected under 35 USC 101 as being directed to non-statutory subject matter, where claims 7-8, 12-13, and 24 appear to define structure with respect to the patient and where claim 65 is claiming a shaved human head and/or wetted hair.

Claims 7, 8, 12, and 13 are canceled. Claims 24 and 65 are amended to overcome the rejection.

Reconsideration of the rejection of claims 24 and 65, as amended, under 35 USC 101 is respectfully requested.

Claims 1-4, 6-21, 24-51, 55-58, 61-74, and 76-90 are rejected under 35 USC 112, first paragraph, on the basis that the specification is not enabling for all conceivable means capable of emitting. Claims 7, 8, 12, 13, 39, 49, and 57 are canceled.

Claim 1 is amended to delete “means”, thereby reciting “emitter” only, which, the Examiner admits, is enabled by the specification. Claims 5, 21, 56, 59, 60, 77, 91, 99, and 100 are similarly amended to delete “means”.

Reconsideration of the rejection of claims 1-4, 6, 9-11, 14-21, 24-38, 40-51, 55-56, 58, 61-74, and 76-90, as amended, under 35 USC 112, first paragraph, is respectfully requested.

Claims 1, 32, 52-54, 65, 75, and 83 are rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claim 32 is amended as suggested by the Examiner.

Claim 83 has been discussed above, and now depends from claim 17, which provides the antecedent basis for beam-forming or beam-steering.

Claims 1 and 52-54 have been amended to delete “means” and to use an appropriate word in its place (e.g., replacing “exchange means” with “exchanger”).

With regard to the antecedent basis of “the emitter” in line 13 of claim 1, this has been overcome by appropriate amendment to the claim.

Claim 65 is amended to refer to the emitter of claim 1.

Claim 75 is amended to delete “therapy delivery means” and to instead refer to the acoustic, ultrasonic or vibratory energy of claim 1.

Reconsideration of the rejection of claims 1, 32, 52-54, 65, 75, and 83, as amended, under 35 USC 112, second paragraph, is respectfully requested.

Claims 1, 7-9, 11, 16-21, 25-32, 35-37, 42-43, 49-51, 54-61, 63, 65-66, 71, 76-78, 81, 83-85, and 89 are rejected under 35 USC 102(e) as being anticipated by Bystritsky (U.S. Patent 7,283,861). Claims 7, 8, 49, and 57 are canceled.

Bystritsky discloses methods for modifying electrical currents in neuronal circuits, such as brain circuits through the simultaneous use of focused ultrasound pulse (FUP) and an existing brain-imaging system, such as functional magnetic resonance imaging (fMRI) system. The methods are used for research, treatment and diagnosis of psychiatric, neurological, and neuro-endocrine disorders whose biological mechanisms include brain circuits. The methods include

the simultaneous step of applying FUP to a live neuronal circuit within a brain and monitoring a brain image produced by a brain imaging system during the application of FUP.

Claim 1, as amended, recites:

An apparatus for providing therapy to a patient having, or who may potentially develop, a neurodegenerative disease characterized by abnormal proteins or prions or related deposits comprising:

(a) emitter to deliver acoustic, ultrasonic or vibratory energy in, into, through, toward, from within or coupled-into a region of the patient's brain or spine which contains, or is in transportable communication with, cerebrospinal fluid (CSF) or blood capable of bearing or bearing a chemical or biological species, reactant, fragment, by-product or species related to the disease;

(b) said at least one emitter operable to at least one of: (1) enhance, promote or enable, directly or indirectly, the formation and/or transport of the species, reactant, fragment or byproduct which is at least ultimately transportable out of a brain or spine region and into a CSF space, lumen, cavity or bloodstream, (2) enhance the transport or mixing of the species within CSF and/or blood or across tissues or existing barriers and membranes, and (3) enhance or promote the increased production of fresh CSF or blood;

(c) said at least one of enhanced formation, transport, mixing or production contributing at least ultimately to some removal of said species from the body and/or at least some immediate or later reduction in concentration of said species in a portion of the body at least in part by using one or more natural paths, emitter-enhanced paths, drug-enhanced paths, surgical or artificial shunts, ports, or internal or external dialysis filters, thereby at least slowing or stopping a disease process;

(d) *said at least one emitter incorporating, is thermally coupled to, or is thermally managed or monitored by a cooling device, temperature control device or temperature monitoring device which controls or monitors the temperature of at least one of (a) at least one emitter, (b) any portion of a patient's anatomy, (c) the temperature or flow of a coolant, and (d) the temperature of an acoustic couplant material juxtaposed to an emitter; and*

(e) said patient optionally receiving a substance before, during or after an operation of the emitter(s) to at least one of: (1) act or help act against a disease process or a contributing factor thereto, (2) promote the formation or transport of a species that is to be removed or is more easily removable than a natural species, (3) encourage or enable growth or regrowth of new or transplanted brain or stem cells or enhance functional brain or neural pathways, (4) encourage or enable the beneficial uptake, processing or interaction of a genetic medicament, and (5) minimize potential or expected side-effects of an emitter exposure or shunting or port procedure., at least one such acting at least one of independently of, in cooperation with, or synergistically with an acoustic exposure.

Bystritsky fails to teach a cooling device, temperature control device, or temperature monitoring device incorporated within the emitter. This feature was recited in claim 22 as filed. Claim 22 was not rejected over Bystritsky and its limitations are now incorporated in claim 1.

Applicant's representative asserts that claims 1, 9, 11, 16-21, 25-32, 35-37, 42-43, 50, 51, 54-56, 58-61, 63, 65-66, 71, 76-78, 81, 83-85, and 89 are not anticipated under 35 U.S.C. §102 by Bystritsky because the Examiner has not demonstrated that Bystritsky teaches a device and method satisfying the requirements of 35 U.S.C. §102 as interpreted by the long standing case law. M.P.E.P. §2131 quotes holdings from cases directed to interpreting and applying 35 U.S.C. §102 as follows:

- (1) a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently, in a single prior art reference *Verdgaal Bros. v. Union Oil Co. of California*, 814 F.2d 628 (Fed. Cir. 1987),
- (2) the identical invention must be shown in as complete detail as is contained in the claim *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989), and
- (3) the elements must be arranged as is required by the claim, *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

With the addition of the cooling device, temperature control device, or temperature monitoring device, claims 1, 9, 11, 16-21, 25-32, 35-37, 42-43, 50, 51, 54-56, 58-61, 63, 65-66, 71, 76-78, 81, 83-85, and 89 are not anticipated under 35 U.S.C. §102 by Bystritsky.

Reconsideration of the rejection of claims 1, 9, 11, 16-21, 25-32, 35-37, 42-43, 50, 51, 54-56, 58-61, 63, 65-66, 71, 76-78, 81, 83-85, and 89, as amended, under 35 USC 102(e) as being anticipated by Bystritsky, is respectfully requested.

Claims 1-6, 10, 12-15, 22-24, 32-34, 35, 38-41, 44-48, 52-54, 62, 64, 67-75, 78-80, 82, 84-88, and 90-101 are rejected under 35 USC 103(a) as being unpatentable over Wallace (U.S. Patent 7,286,879) in view of Shalev (U.S. Patent Pub. No. 2003/0176892). Claims 12, 13, 22, and 39 are canceled.

The present application was filed on January 29, 2004, and is a CIP of application Serial No. 10/612,171, filed July 1, 2003. Wallace, the primary reference, was filed on July 16, 2004, nearly six (6) months *after* the filing of the present application. There does not appear to be any information on the face of the patent indicating that Wallace has an earlier priority date than Applicants' filing date. Thus, the primary reference cannot be used in the combination of references to reject the claims. Further, Shalev, the secondary reference, is used to disclose aspects of Applicants' claims not disclosed by Wallace. With Wallace unavailable as

the primary reference, and since Shalev by itself fails to disclose or suggest Applicants' claims, then the rejection must fall.

Reconsideration of the rejection of claims 1-6, 10, 14, 15, 23, 24, 32-34, 35, 38, 40, 41, 44-48, 52-54, 62, 64, 67-75, 78-80, 82, 84-88, and 90-101, as amended, under 35 USC 103(a) as being unpatentable over Wallace in view of Shalev is respectfully requested.

Since claims 2-6, 10, 14-15, 23, 24, 33-34, 38, 40, 41, 44-48, 52-53, 62, 64, 67-70, 72-75, 79-80, 82, 86-88, and 90-101 were not rejected under Bystritsky and cannot be properly rejected under the combination of Wallace and Shalev, then at least these claims should be patentable. In addition, the amendment to claim 1 to overcome Bystritsky is considered to render claims 1, 9, 11, 16-21, 25-32, 35-37, 42-43, 50, 51, 54-56, 58-61, 63, 65-66, 71, 76-78, 81, 83-85, and 89 also patentable.

The foregoing amendments and arguments are submitted to place the application in condition for allowance. The Examiner is respectfully requested to take such action. If the Examiner has any questions, he is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,

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